

	<b>Regulatory Standards Division</b> <b>AMA-200</b>	<b>Document #</b> <b>WI 214.04</b>	<b>Revision</b> <b>Original</b>
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REVISION HISTORY			
Rev	Description of Change	Author	Effective Date
A	Original	JLA	06/24/03
1	Renumber	JLA	01/22/2004
2	Update Hyperlinks	DAW	06/09/2006

REFERENCE DOCUMENTS	
Document Number	Document Title
<a href="#">QMS 200</a>	AMA-200 Quality Systems Manual
<a href="#">QP214</a>	Product Development Procedure

Documents referenced in this work instruction are applicable to the extent specified herein.

## 1. Purpose

This work instruction describes the process by which a product development plan is changed.

## 2. Scope

This work instruction applies to changes of a product development plan and the completion of QF 214.04, Plan Change Request (PCR).

## 3. Definitions and Acronyms

There are no unique definitions or acronyms related to this document.

## 4. Flowchart

There is no flowchart required for this document.

## 5. Responsibilities

- 5.1 The Originator is responsible for the initiation of QF 214.04 and the completion of Step 1.
- 5.2 The Project Coordinator is responsible for:
  - 5.2.1 The initial review of QF 214.04 and the completion of step 2.
  - 5.2.2 The timely implementation of the change and the completion of QF 214.04, Step 5.

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- 5.3 The Assigned Assistant Manager is responsible for the review of QF 214.04 and the completion of Step 3.
- 5.4 The Leadership team is responsible for the review and approval of the change.
- 5.5 The Management Representative is responsible for the completion of QF 214.04, Step 4.

## 6. Work Instructions

- 6.1 A QF 214.04 may be initiated by anyone involved in a specific project.
- 6.2 The process for changing a plan is as follows:
  - 6.2.1 The Originator completes Step 1 of QF 114.04, signs it and forwards it to the PC.
  - 6.2.2 The PC will review the proposed change and complete Step 2 of QF 114.04.
    - 6.2.2.1 The PC will determine whether the proposed change is major, minor/maintenance, or administrative and check the appropriate box.
    - 6.2.2.2 The outcome of the review will be one of the following:
      - 6.2.2.2.1 An accepted request will be signed and forwarded to the Assigned Branch Manager for review.
      - 6.2.2.2.2 A rejected request will be returned to the originator for disposal or correction. The PC will include a reason for the rejection in the appropriate block.
  - 6.2.3 The Assigned Branch Manager will review the form and complete step 3 in QF 214.04.
    - 6.2.3.1 The outcome of the review will be one of the following:
      - 6.2.3.1.1 An accepted request will be signed and forwarded to the Leadership Team for review and approval.
      - 6.2.3.1.2 A rejected request will be returned to the PC for disposal or correction. The Assigned Branch Manager will include a reason for the rejection in the appropriate block.
  - 6.2.4 The Leadership Team will review the form and the Management Representative will complete step 4 in QF 214.04.
    - 6.2.4.1 The outcome of the review will be one of the following:

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6.2.4.1.1 An approved request will be signed and forwarded to the Assigned Branch Manager/PC for implementation.

6.2.4.1.2 A rejected request will be returned to the Assigned Branch Manager/PC for disposal or correction. The Management Representative will include a reason for the rejection in the appropriate block.

6.2.5 The PC will implement the approved change upon receipt and complete Step 5 of QF 214.04.

6.2.5.1 The PC will brief the appropriate personnel regarding the specifics of the change to the plan.

## 7. Metrics

There are no metrics required for this document.

## 8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
QF 214.04	Plan Change Request (PCR)	Five Years

Quality forms are found in Appendix 1 of the AMA-200 QSM.